SCHOTT

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

From: Robert W. Swift
Date: January 25, 2002

Subject: Docket Number 01D-0510
Ref. Draft Guidance *Integration of Dose-Counting Mechanisms into MDI Drug Products*

Dear Sir or Madam,

We applaud FDA's efforts, as shown by this draft guidance, to provide MDI users with a reliable, user-friendly way to know when their MDI's can no longer be trusted to deliver the intended dose. As a packaging component manufacturer, we also appreciate the opportunity to comment on the draft.

The Background section describes very well the reasons MDI's become unreliable before they are empty and the corresponding risks / poor alternatives for patients. This information provides an excellent technical argument for recommending some form of feedback to the patient about the number of doses or amount of formulation remaining. Our comments concern the recommendation of and implied support for one specific solution to the problem.

The boxed notice just before the Introduction states that other approaches may be used. Yet, the guidance specifically recommends the use of dose-counting mechanisms without mentioning any other suitable solutions. As the title suggests, the document provides useful implementation guidance for manufacturers who choose dose-counters. However, in our view, it should not recommend dose-counters as the preferred solution. We are concerned the guidance will be interpreted as an endorsement for dose counters to the exclusion of other approaches. Therefore, we encourage you to more clearly indicate within the body of the document that dose counters are only one acceptable solution.

An alternative is a container system that permits visual verification of the level of formulation remaining. Schott's PURGARD® container is an example of this approach. Its combination of a USP Type I clear or amber inner glass vial and a translucent outer polymer shell allows a quick visual check of the remaining formulation. The "minimum recommended level" can be indicated on the label or incorporated into the container or mouthpiece design.

If you have questions or need further information regarding our comments, please feel free to contact us at your convenience.

Best regards,

Robert W. Swift
Scientific Services
Schott Pharmaceutical Packaging

01D-0510 C2

Cc. R Hormes – Schott Glaskontor

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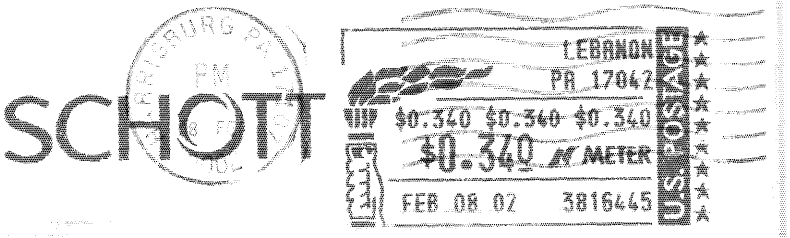

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